Asian Journal of Medical and Pharmaceutical Sciences
https://doi.org/10.30904/j.ajmps.2026.4967 | E-ISSN: 2348-0165

Formulation and Evaluation of Metoprolol Succinate Buccal Adhesive Tablets Using Natural Polymers

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Received: 10-02-2026 | Revised: 27-02- 2026 | Accepted: 31-03-2026 | Published: 25-04-2026

ABSTRACT
Buccoadhesive tablets were formulated using an active drug and mucoadhesive polymers to prolong drug residence in the buccal cavity, with mannitol incorporated to mask the drug's taste; in this study, Metoprolol succinate was selected as the model drug, and both natural (NBA01, NBA02, NBA03, NBA04) and synthetic polymers (HPMC K100M, Eudragit RS100, Poloxamer 407) were evaluated. The natural polymers were characterized for phytochemical constituents, swelling index, particle size distribution, derived properties, moisture content, pH, and microbial load, and were found satisfactory for formulation development. Buccal tablet formulations were prepared as MNF1–MNF4 (NBA01), MNF5–MNF8 (NBA02), MNF9–MNF12 (NBA03), and MNF13–MNF16 (NBA04), while synthetic polymer-based formulations were prepared as MSF1–MSF3 (HPMC K100M), MSF4–MSF6 (Eudragit RS100), and MSF7–MSF9 (Poloxamer 407). Compatibility studies confirmed no significant interactions between drug and polymers, and both precompression and postcompression parameters were within acceptable limits, indicating suitability of the developed formulations for further evaluation.
Keywords: buccal cavity, moisture content, swelling index, particle size distribution, derived properties, microbial load

1. Introduction

The development of dosage forms has evolved to meet therapeutic needs, ensuring efficacy, stability, cost-effectiveness, and targeted drug delivery with minimal side effects Conventional dosage forms have largely been replaced by novel drug delivery systems (NDDS), which enhance drug stability, bioavailability, and therapeutic performance. Among these, buccal adhesive drug delivery systems have gained significant attention [1–4].

The oral route remains the most preferred due to its convenience and patient compliance, despite certain limitations. The oral mucosa offers a promising site for sustained drug delivery, enabling controlled release into systemic circulation [5]. Various dosage forms such as mouthwashes, lozenges, gels, chewing gums, films, and patches have been developed for buccal delivery [6]. However, conventional systems are often limited by rapid drug clearance due to saliva, leading to reduced therapeutic efficacy [7,8]. To overcome this, bioadhesive systems have been designed to prolong drug residence time in the buccal cavity [9].

Bioadhesion is the process by which polymers adhere to biological surfaces, such as mucosal tissues, through interfacial forces, resulting in prolonged retention [10]. Several theories, including adsorption, diffusion, wetting, fracture, and electronic theories, explain this phenomenon [11,12]. Bioadhesive formulations utilize hydrophilic polymers that swell upon hydration, enhancing adhesion. Ideal polymers should possess properties such as hydrophilicity, flexibility, hydrogen bonding ability, and viscoelasticity [13,14]. These polymers may be natural or synthetic, and are selected to improve drug absorption by increasing mucosal contact time. The bioadhesive strength depends on polymer characteristics (molecular weight, concentration, flexibility) and environmental factors (pH, contact time, swelling, and physiological conditions) [15–17].

Evaluation methods include swelling studies, viscosity measurement, shear stress analysis, and detachment force testing.In this study, both natural and synthetic polymers were evaluated for their bioadhesive properties. Buccal formulations were developed, compared, and optimized, followed by in vivo evaluation.

2. Materials and Methods

2.1 Materials:

Metoprolol succinate procured from MSN Laboratories, Hyderabad, Poloxomer-407, Eudragit RS100 from Yarrow Chemie Pvt. Ltd, Mumbai, Hydroxy propyl methyl cellulose K 100 M, Ethyl cellulose (30-50cps), Lactose (SD) from Loba Chemie Pvt.Ltd, Mumbai.

2.2 Methods:

2.2.1 Preformulation studies

Collection and Extraction of natural buccadhesive materials

The bark of *G. damine*, dried gummy exudates of *H. laurina*, and seeds of *A. marmelos* and *P. dulce* were collected from various regions of Andhra Pradesh (Figs-1,2). The dried materials were pulverized and dispersed in demineralized water using an impeller. The resulting mucilage was filtered through muslin cloth to remove fibrous matter and subsequently

centrifuged. Gum extraction was carried out using 96% ethanol/acetone, followed by redispersion in water and re-extraction. The purified gum was dried at 50 °C for 8 h. Further purification was achieved using 0.1 M sodium hydroxide or hydrochloric acid, followed by ethanol extraction. However, such treatments may alter the physicochemical properties of the material. The isolated gums were coded as follows: NBA01 (*G. damine*), NBA02 (*H. laurina*), NBA03 (*A. marmelos*), and NBA04 (*P. dulce*).

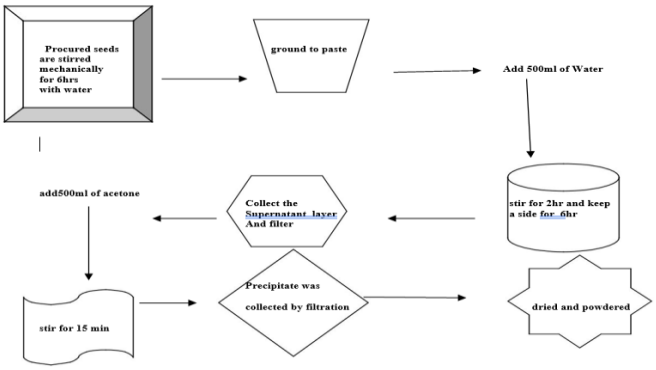
Procured seeds are stirred mechanically for 6hrs with water
ground to paste
Add 500ml of Water
stir for 2hr and keep a side for 6hr
Collect the Supernatant layer And filter
add500ml of acetone
stir for 15 min
Precipitate was collected by filtration
dried and powdered

Fig 1: Isolation of Mucoadhesive Material from *Aegle Marmelos* and *P. Dulce* seed

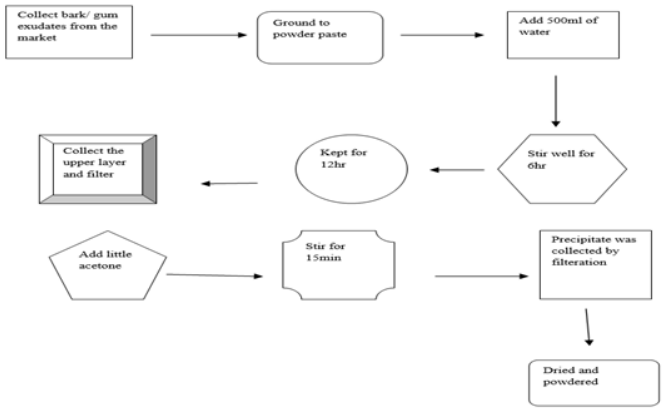
Collect bark/ gum exudates from the market
Ground to powder paste
Add 500ml of water
Stir well for 6hr
Kept for 12hr
Collect the upper layer and filter
Add little acetone
Stir for 15min
Precipitate was collected by filteration
Dried and powdered

Fig 2: Isolation of Mucoadhesive Material from *G. Damine* and *H. Laurina*

General characterization of natural buccal adhesive materials of NBA01, NBA02, NBA03 and NBA04

Identification tests for hydrocolloid

The extracted powder was mixed with ruthenium red, mounted with a cover slip, and treated with lead acetate; excess stain was removed, resulting in a pink coloration indicating hydrocolloids. In another test, the powder was mixed with corallin soda, treated with 25% sodium carbonate, and observed for pink staining. Additionally, the powder was boiled in distilled water, producing a gelatinous mass upon cooling. These procedures were applied to NBA01–NBA04, and all samples were confirmed as hydrocolloids.

Identification of phytochemical constituents

The extracted powders were subjected to qualitative phytochemical analysis using standard procedures. Alkaloids were identified by Hager's test, where a yellow precipitate confirmed their presence. Carbohydrates were detected using Benedict's test, indicated by an orange-red precipitate. Flavonoids were confirmed by the alkaline reagent test, showing a yellow color that became colorless upon acidification. Tannins were identified by lead acetate test (precipitate formation) and ferric chloride test, which produced green, purple, blue, or black coloration.

Formulation of Buccal adhesive tablets of Metoprolol using NBA01, NBA02, NBA03, NBA04, HPMCK100M, EUDRAGITRS100 and POLAXOMER407

Buccaladhesive tablets of metoprolol (50 mg) were prepared by the wet granulation method using NBA01–NBA04, HPMC K100M, Eudragit RS100, and Poloxamer 407 (Tables 1, 2). A total of 15 batches (100 tablets each) were formulated. Drug–polymer blends with ethyl cellulose (as backing layer) were granulated using water. The wet mass was passed through a 12-mesh sieve, dried at 60 °C for 4 h, and re-sieved through 16 mesh. The dried granules were lubricated with talc and magnesium stearate, blended for 5 min, and compressed using a Karnavati tablet compression machine with 9 mm flat punches to a hardness of 7–8 kg/cm². Precompression parameters were evaluated, and the tablets were characterized for hardness, friability, disintegration time, drug content, and drug release.

Table 1: Formulation of Buccal adhesive tablets of metoprolol succinate prepared by using natural polymers

S. No.	Ingredients (mg/tablet)	Formulation Code														
		MNF1	MNF2	MNF3	MNF4	MNF5	MNF6	MNF7	MNF8	MNF9	MNF10	MNF11	MNF12	MNF13	MNF14	MNF15	MNF16
1.	METOPROLOL	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50
2.	NBA-01	100	75	50	25	-	-	-	-	-	-	-	-	-	-	-	-
3.	NBA-02	-	-	-		100	75	50	25	-	-	-	-	---	-	-	-
4.	NBA-03		-	-	-	-	-			100	75	50	25	-	-	-	
5.	NBA-04	-	-	-	-	-	-	-	-	-	-	-	-	100	75	50	25
6.	MANNITOL	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
7.	ETHYL CELLULOSE	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20
8.	DCP	10	35	60	85	10	35	60	85	10	35	60	85	10	35	60	85
9.	MAGNESIUM STEARATE	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
10.	TALC	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	Total(mg)	200	200	200	200	200	200	200	200	200	200	200	200	200	200	200	200

Table 2: Formulation of buccal adhesive tablets of metoprolol prepared by using synthetic polymers

S. No.	Ingredients (mg/tablet)	Formulation code								
		MSF01	MSF02	MSF03	MSF04	MSF05	MSF06	MSF07	MSF08	MSF09
1.	METOPROLOL	50	50	50	50	50	50	50	50	50
2.	HPMCK100M	100	75	50	-	-	-	-	-	-
3.	EUDRAGITRS100	-	-	-	100	75	50	-	-	-
4.	POLOXAMER407		-	-	-	-	-	100	75	50
5.	DCP	10	35	60	10	35	60	10	35	60
6.	MAGNESIUM STEARATE	5	5	5	5	5	5	5	5	5
7.	TALC	5	5	5	5	5	5	5	5	5
8.	ETHYL CELLULOSE	20	20	20	20	20	20	20	20	20
9.	MANNITOL	10	10	10	10	10	10	10	10	10
	Total(mg)	200	200	200	200	200	200	200	200	200

Shear stress measurement

Buccoadhesive strength was evaluated using a two-glass plate apparatus, where polymer solutions (1–3% w/v) were placed between plates and detachment force was measured using incremental weights. Contact time was varied, and the weight required to separate the plates was recorded. Higher detachment weight indicated stronger adhesion, and comparative analysis was performed for NBA01–NBA04, HPMC K100M, Eudragit RS100, and Poloxamer 407.

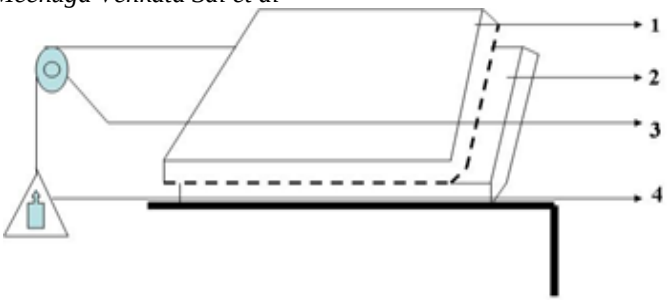

Fig.3: Apparatus for Shear stress measurement

Wilhelmy's apparatus

Buccoadhesive strength was measured using a glass plate apparatus immersed in buccal solution, balanced with a pulley system (fig 2). A 1% w/v polymer-coated plate (dried at 60 °C) was immersed for specified times, and detachment force was determined by adding weights. The weight required to pull the plate out indicated adhesion strength, and the study was performed for NBA01, NBA02, HPMC K100M, and Eudragit RS100.

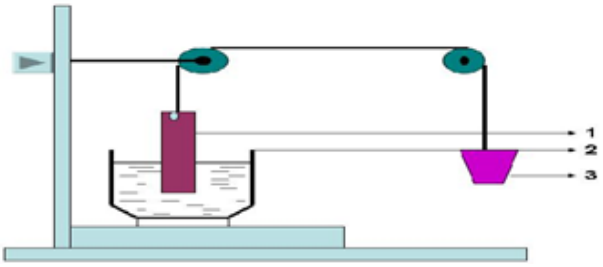

Fig. 4: Wilhelmy's Apparatus

Interaction study by FTIR

IR spectroscopy studies were carried out using Perkin Elmer model 2000 by KBr pellet method. The IR spectrum was recorded from the range of 4000 to 400 cm-1 and peaks obtained were identified.

Interaction study by DSC

Differential scanning colorimetric analysis were performed to characterize the drug polymer compatibility. The DSC thermograms of pure drug (metoprolol Succinate), polymers (NBA01, EUDRAGITRS100, HPMCK100M, NBA02, NBA03, NBA04, POLAXOMER 407) and drug-polymer blends were recorded in a DSC analyzer Model DSC-50 Shimadzu.

Swelling Index

Swelling studies were performed by placing 100 mg of buccoadhesive material in 10 ml distilled water, shaking intermittently for 1 h, and allowing it to stand for 3 h, with periodic removal of excess water. The increase in weight was recorded, and the experiment was conducted in triplicate to obtain mean values. The same procedure was applied for all polymers in pH 1.2 and 7.4, and swelling index (SI) was calculated as percentage weight gain.

$$\text{Swelling index (S.I)} = \{(W_t - W_o)/W_o\} \times 100$$

Where S.I=Swelling index

W_t=Weight of tablet at time t

W_o= Weight of tablet before immersion

Evaluation of Tablets

Tablets formulated were studied for weight variation, hardness, thickness, friability and disintegration time in water, 0.1N HC1 and pH 6.8 buffer.

Estimation of Drug content in the Tablets: Five metoprolol tablets were weighed, powdered, and an amount equivalent to 10 mg drug was transferred to a 25 mL volumetric flask. The drug was dissolved in methanol with heating, volume made up, and suitably diluted with phosphate buffers (pH 1.2 6.8). The solution was analyzed spectrophotometrically at 274 nm for drug content.

Drug Release Study

Drug release from metoprolol tablets (50 mg) was studied using USP dissolution apparatus in 900 ml of pH 1.2 and pH 6.8 media at 37 ± 0.5°C and 100 rpm. Samples were withdrawn at predetermined intervals, filtered, diluted, and analyzed at 274 nm using a Shimadzu UV spectrophotometer. All experiments were performed in triplicate.

Analysis of Release Data

The order of drug release from buccaladhesive systems was described by using zero-order kinetics or first orders kinetics. The mechanism of drug release from buccal tablets was studied by using Higuchi equation and Peppas-Korsemeyer equation.

3. Results and Discussion

Table 3: List of phytochemical constituents identified

Tests	Results			
	NBA01	NBA02	NBA03	NBA04
Alkaloids	-	—	-	-
Carbohydrates	+	+	+	+
Flavonoids	-	—	-	-
Tannins	-	-	-	-

Table 4: Swelling Index of NBA01, NBA02, NBA03 and NBA04

Parameter	Result			
	NBA01	NBA02	NBA03	NBA04
Swelling index (after 3hr)				
At, Distilled water	26.09 ± 0.34	24.24 ± 34.3	23.12 ± 0.47	12.16 ± 0.26
pH – 1.2	19.33 ± 0.28	16.92 ± 28.2	15.23 ± 0.35	10.76 ± 0.35
pH – 6.8	24.12 ± 0.29	19.29 ± 29.1	18.12 ± 0.32	11.14 ± 0.23

Table 5: Characterization of NBA01, NBA02, NBA03 and NBA04

Property	Results Obtained			
	NBA01	NBA02	NBA03	NBA04
Tapped density(gm/cc)	0.702±0.02	0.715±0.36	0.615±0.14	0.74±0.22
Bulk density (gm/cc)	0.632±0.04	0.618±0.02	0.623±0.15	0.603±0.66
Bulkiness (cc/gm)	1.58±0.04	1.60±0.45	1.51±0.66	1.56±0.81
Angle of repose(^{0})	28.20±1.28	26.12±0.66	27.33±0.51	25.60±0.33
Compressibility index (%)	10.45±1.34	9.33±0.25	10.51±0.61	10.37±0.47
Hausner's ratio	1.2±1.54	1.1±0.56	1.02±0.42	1.3±0.51
Moisture content	14.96±1.12	12.12±0.56	12.32±0.15	11.47±0.33

Table : Comparison of Buccal Adhesive properties of Natural and Synthetic polymers

Report of shear stress measurement

		Weight required to detach glass plate (gms) At the time intervals		
	Concentrations (%w/v)	15min	30min	60min
NBA01	1	141.37 ± 1.37	163.38 ± 1.86	209.02 ± 2.06
	2	192.23 ± 1.69	210.66 ± 2.37	261.76 ± 2.06
	3	206.92 ± 2.86	240.00 ± 0.58	284.39 ± 3.35
NBA02	1	84.542 ± 1.45	124.25 ± 1.75	175.04 ± 2.15
	2	119.54 ± 1.50	162.54± 2.54	210.78± 2.06
	3	141.12 ± 2.56	196.35 ± 0.75	247.30 ± 3.35
NBA03	1	138.22 ± 0.36	153.16 ± 0.23	205.22 ± 1.99
	2	196.32±0.68	212.33 ± 0.36	243.35 ± 0.77
	3	208.41 ± 1.99	242.00 ± 0.29	276.36 ± 0.56
NBA04	1	86.45 ± 0.33	128.33 ± 0.99	176.33± 0.38
	2	120.12 ± 0.36	168.46± 0.88	211.23± 0.35
	3	147.54± 0.35	201.65 ± 0.11	249.30 ± 0.75
POLOXAMER407	1	89.36 ± 0.75	125.25 ± 0.33	176.04 ± 0.88
	2	120.77± 0.90	165.54± 0.54	219.78± 0.36
	3	149.12 ± 0.66	197.35 ± 0.51	242.30 ± 2.35
HPMCK100M	1	83.08 ± 0.20	130.16 ± 0.43	170.61 ± 0.96
	2	117.64 ± 1.67	159.89 ± 1.50	208.13 ± 1.49
	3	139.50 ± 0.43	187.18 ± 1.81	243.36 ± 0.09
EudragitRS100	1	163.90 ± 0.76	185.32 ± 0.45	212.90 ± 2.04
	2	206.12 ± 0.83	223.26 ± 3.72	232.92 ± 0.04
	3	231.77 ± 2.11	241.65 ± 2.87	254.62 ± 0.89

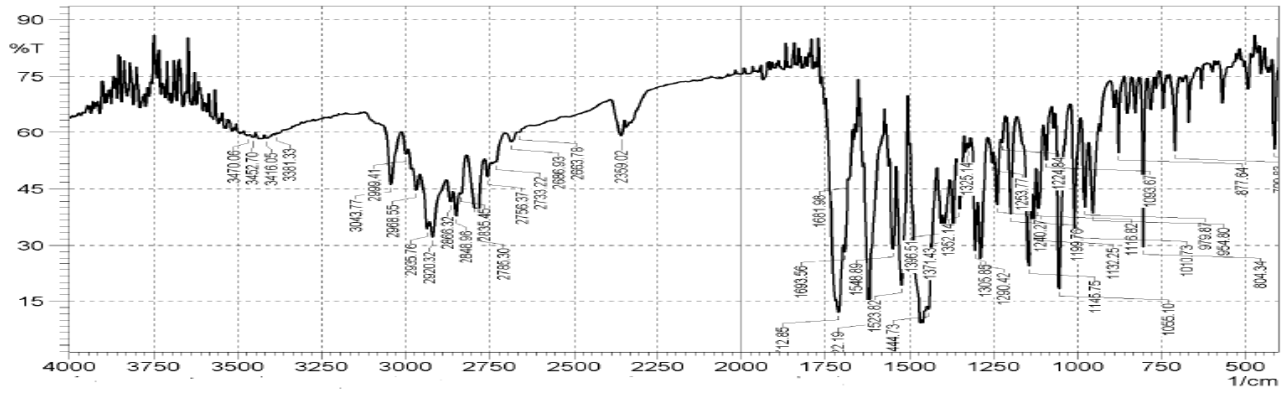

Fig.5: FTIR of optimized formulation

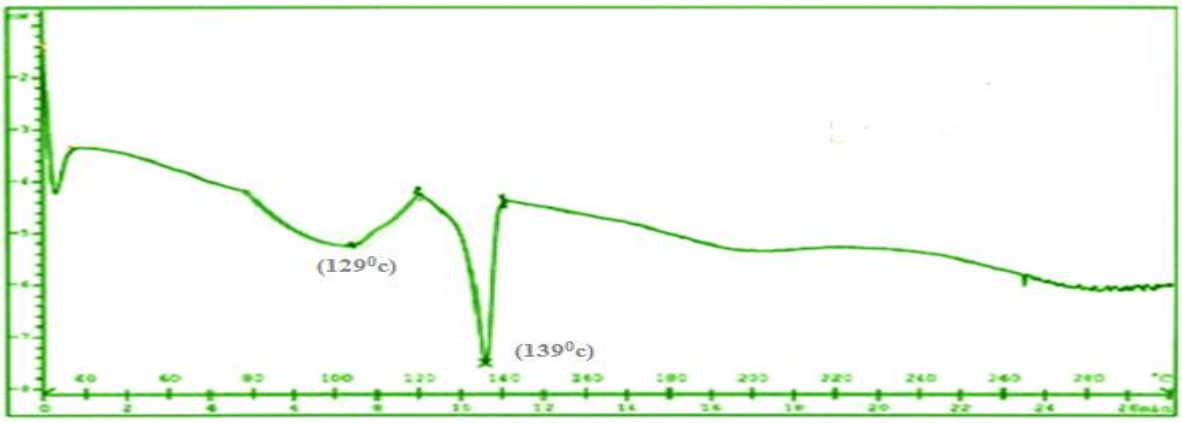

Fig:6: DSC of optimized formulation

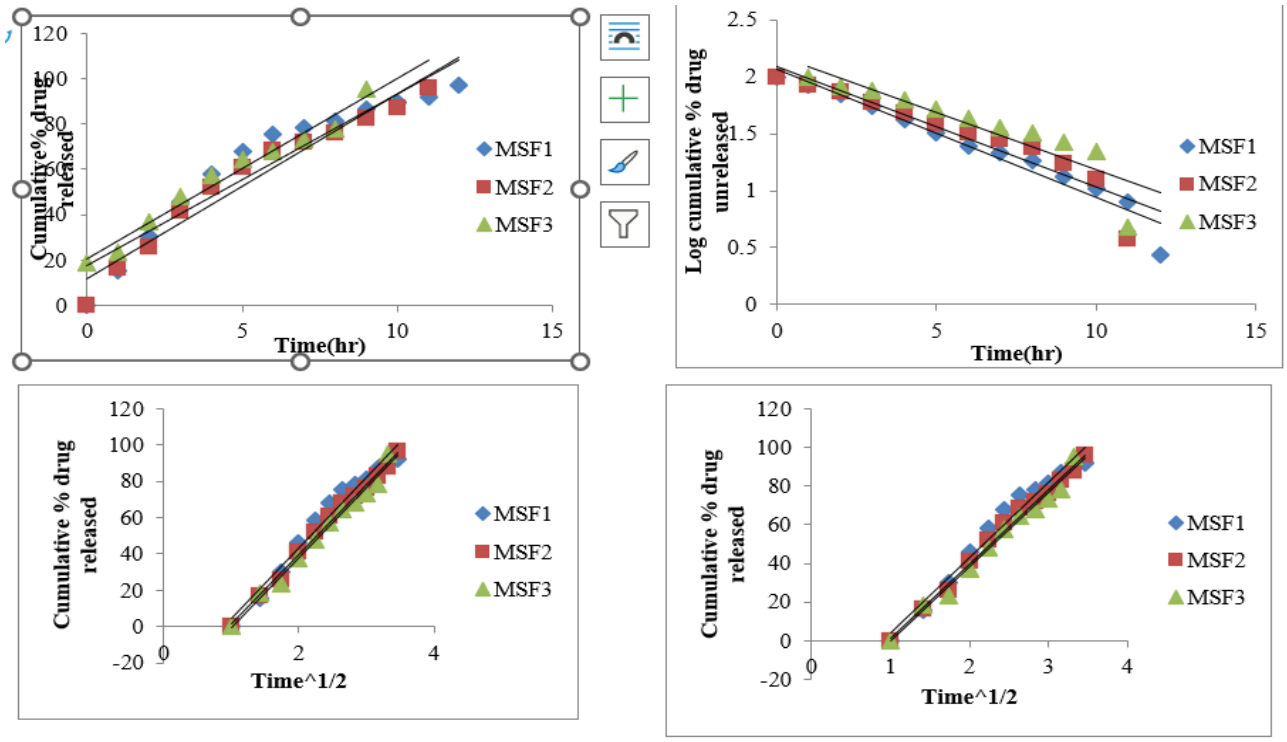

Fig.7: Cumulative % drug released from MSF1-MSF3

4. Discussion

Mucilages (bucopolysaccharides) from natural edible sources were selected for buccal drug delivery due to their binding ability, safety, availability, and cost-effectiveness, and were extracted using aqueous methods followed by solvent precipitation to preserve their stability and ensure good handling properties. Preformulation studies confirmed that the isolated gums (NBA01–NBA04) were polysaccharides with suitable pH, swelling behavior, flow properties, solubility, and low microbial load, making them appropriate for mucoadhesive applications; among them, NBA01 showed superior swelling and adhesion characteristics. Buccal tablets of Metoprolol succinate were formulated using both natural and synthetic polymers (HPMC K100M, Eudragit RS100, Poloxamer 407), and all pre- and post-compression parameters were within acceptable limits. Drug release studies demonstrated that swelling index significantly influenced release behavior, with higher polymer concentrations leading to increased swelling, thicker gel formation, and consequently slower drug release; formulations MNF1 (natural polymer) and MSF1 (synthetic polymer) exhibited optimal performance. FTIR and DSC analyses confirmed compatibility between drug and excipients, while kinetic studies revealed that all formulations followed zero-order release with non-Fickian diffusion mechanisms. Overall, natural polymer NBA01 exhibited better mucoadhesive strength and controlled drug release compared to other natural and synthetic polymers, highlighting its potential as an effective excipient in buccal drug delivery systems.

5. Conclusion

The present research work was planned to prepare a buccaladhesive tablets by using natural and synthetic gums, the usage of natural gums were more safe when compared to synthetic, the reason behind this was since they were natural and

easily compatable to the body nature. Several formulations were prepared; it was clearly observed that the formulations prepared by using NBA01 were most suited for Metoprolol.

Acknowledgment
The authors thank the Vasavi institute of Pharmaceutical Sciences, Vasavi Nagar, Peddapalli, Kadapa, A.P, India, for technical assistance and support.

Conflict of Interests
The authors declare no conflict of interest

Ethics Approval: Not applicable

Funding
This study received no specific funding from public, commercial, or not for profit funding agencies.

AI Tool Declaration
The authors declare that no AI and related tools are used to write the scientific content of this manuscript.

Data Availability
Data will be available on request

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